

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 4649-4000PC	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US05/06930	International filing date (<i>day/month/year</i>) 03 March 2005 (03.03.2005)	(Earliest) Priority Date (<i>day/month/year</i>) 03 March 2004 (03.03.2004)
Applicant ESSENTIA BIOSYSTEMS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐

With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐

Certain claims were found unsearchable (See Box No. II)

3. ☒

Unity of invention is lacking (See Box No. III)

4. ☒

With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. ☒

With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. ☐

With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.

b. ☒

none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1-3,7-33,68-75,78-80 and 197-211
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐

The additional search fees were accompanied by the applicant's protest.

☐

No protest accompanied the payment of additional search fees.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/00, 39/02

US CL : 514/2, 951; 530/300, 350; 424/236.1, 278.1, 405

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/2, 951; 530/300, 350; 424/236.1, 278.1, 405

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/072049 A2 (ESSENTIA BIOSYSTEMS, INC.) 04 September 2003, claims 19-23, and pages 12-15 and 36-37.	1-3, 8-16, 22-29, 78-80, 203-204 and 206-
X	SCHWARTZ J. J. et al. Peptide-mediated cellular delivery. Curr Opin Mol Ther. 2000, Vol. 2, No. 2, pages 162-167, entire document, especially abstract and Table 2.	1-11, 22-23, 28-33, 197-198 and 203-208
X	US 2003/0104622 A1 (ROBBINS) 05 June 2003, claims 6-9, 12-13 and 25-29, and Tables 6-7 and Example 4, paragraph [0183].	1-3, 8-9, 68-73, 74-75, 78-80, and 197-208
X	WO 00/34308 (WASHINGTON UNIVERSITY) 15 June 2000, claims 1-2, 65, 72 and 99.	204-208
X	US 61217912 B1 (PARK et al.) 17 April 2001, claims 1-4 and Figure 1.	197 and 209
X	US 2001/0024716 A1 (CHEN et al.) 27 September 2001, paragraphs [0094-0095].	197, 206-207 and 209-211
X	WO 02/07773 A2 (ESSENTIA BIOSYSTEMS, INC.) 31 January 2002, claims 1-3, 11-17, 28, 33, 39, and pages 8-10.	1-3, 7-15, 22-29, 31-33, 68-71, 73-75, 78-80, 197-204 and 206-207



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 August 2005 (22.08.2005)

Date of mailing of the international search report

27 DEC 2005

Name and mailing address of the ISA/US

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C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 6696038 B1 (MAHATO et al.) 24 February 2004, Example 13, abstract, and columns 3 and 9.	1, 16-19. ----- 1, 16-21
X	US 2003/0118598 A1 (HUNT) 26 January 2003, paragraphs [0190, 0199, 0110 and 0142] and claims 1-12.	1-3, 7-9, 68-73
X	US 2004/0009469 A1 (APT et al.) 15 January 2004, paragraphs [0422 and 0424] and abstract.	1, 72 and 74-75.
X	US 5985434 A (QIN et al) 16 November 1999, claims 15-16.	197, 206-207 and 209-211
Y	US 4434228 (SWANN) 28 February 1984, paragraphs [422-0424] and abstract.	1, 16 and 17-21

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BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

which has a positively charged backbone, and a kit comprising the composition thereof.

Group 1, claims 1-3, 7-33, 68-75 and 197-211, drawn to a composition comprising a polypeptide and a carrier which has a positively charged backbone, and a kit comprising the composition thereof.

Group 2, claims 4-6, 34-67, 182-185 and 197-211, drawn to a composition comprising a non-polypeptide or/and non-polynucleotide agent and a carrier which has a positively charged backbone.

Group 3, claims 76-77 and 186-189, drawn to a kit comprising a device for delivering a biologically active protein to a subject and a composition comprising a positively charged carrier.

Group 4, claims 78-80, drawn to a method of administering a biologically active protein to a subject comprising delivering the protein and a positively charged carrier to the skin or epithelium of the said subject.

Group 5, claims 81-97 and 190-196, drawn to a method of administering a non-protein non-nucleic acid molecule to a subject comprising delivering the molecule and a positively charged carrier to the skin or epithelium of the said subject.

Group 6, claims 98-140, drawn to a composition comprising an antigen for immunization and a carrier which has a positively charged backbone.

Group 7, claims 141-181 and 184, drawn to a method of administering the antigen for immunization and a positively charged carrier to the skin or epithelium of the said subject.

Group 8, claim 212, drawn to a composition comprising a non-covalent complex comprising (i) a positively charged backbone, and (ii) at least two of members: (a) a negatively charged backbone having a plurality of attached imaging moieties, (b) a negatively charged backbone having a plurality of attached targeting moieties, (c) polynucleotide, and/or (d) a negatively charged backbone having a plurality of attached biological agent.

Group 9, claim 213, drawn to a method of preparing a composition comprising a positively charged backbone and at least two of members: (a) a negatively charged backbone having a plurality of attached imaging moieties, (b) a negatively charged backbone having a plurality of attached targeting moieties, (c) polynucleotide, and/or (d) a negatively charged backbone having a plurality of attached biological agent.

Group 10, claims 214-218, drawn to a composition comprising insulin and a carrier having positively charged backbone, and a kit comprising said composition.

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Group 11, claims 219-220, drawn to a method of administering the insulin to a subject comprising delivering to the subject the insulin and a positively charged carrier.

Group 12, claims 221-228, drawn to a composition comprising imaging agent and a targeting agent and a positively charged backbone, and a kit comprising said composition.

Group 13, claims 229-238, drawn to a method of administering the composition of Group 12 to a subject comprising delivering to the skin or epithelium of subject the said composition.

Group 14, claim 239, drawn to a composition comprising a positively charged backbone and at least two of members: (a) a negatively charged backbone having a plurality of attached imaging moieties, (b) a negatively charged backbone having a plurality of attached targeting moieties, (c) a negatively charged backbone having a plurality of attached biological agent.

Group 15, claim 240, drawn to a method of preparing the composition of Group 14 to a subject comprising combining a positively charged backbone component and at least two of members: (a) a negatively charged backbone having a plurality of attached imaging moieties, (b) a negatively charged backbone having a plurality of attached targeting moieties, (c) a negatively charged backbone having a plurality of attached biological agent.

The inventions listed as Groups 1-15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group 1 is directed to a composition comprising bioactive polypeptide and a carrier which has a positively charged backbone, which is not a contribution over the prior art as Waugh et al. (WO 03072049) patent application teaches a composition comprising a biologically active polypeptide, i.e., vascular endothelial growth factor (VEGF), and a carrier molecule which structure reads on the peptide formula set forth in instant claim 29; the said carrier molecule comprises a positively charged backbone having a plurality of attached efficiency groups (see the patent claim 19) wherein association between the VEGF and the carrier molecule is non-covalent. The Waugh et al. teachings are applied to instant claims 1-3 and 22. Thus, the invention lacks unity of invention.

Continuation of B. FIELDS SEARCHED Item 3:

Databases: Medline, US Pre-Grant publication Full-Text database, US Patent Full-Text database, EPO Abstracts database, JPO Abstracts database, Derwent World Patent Index, and, issued patents AA, pending patents AA and Genbank (for sequence search). [STIC-structural search for the peptide formulas set forth in claims 29 and 204]

Search terms: HIV-TAT or fragment thereof, human immunodeficiency virus-1 tat, trans-activating protein; antennapedia PTD (protein trans-activating domain); polylysine; polyarginine; polyalkyleneimine or polyethyleneimine; and, botulinum toxin.